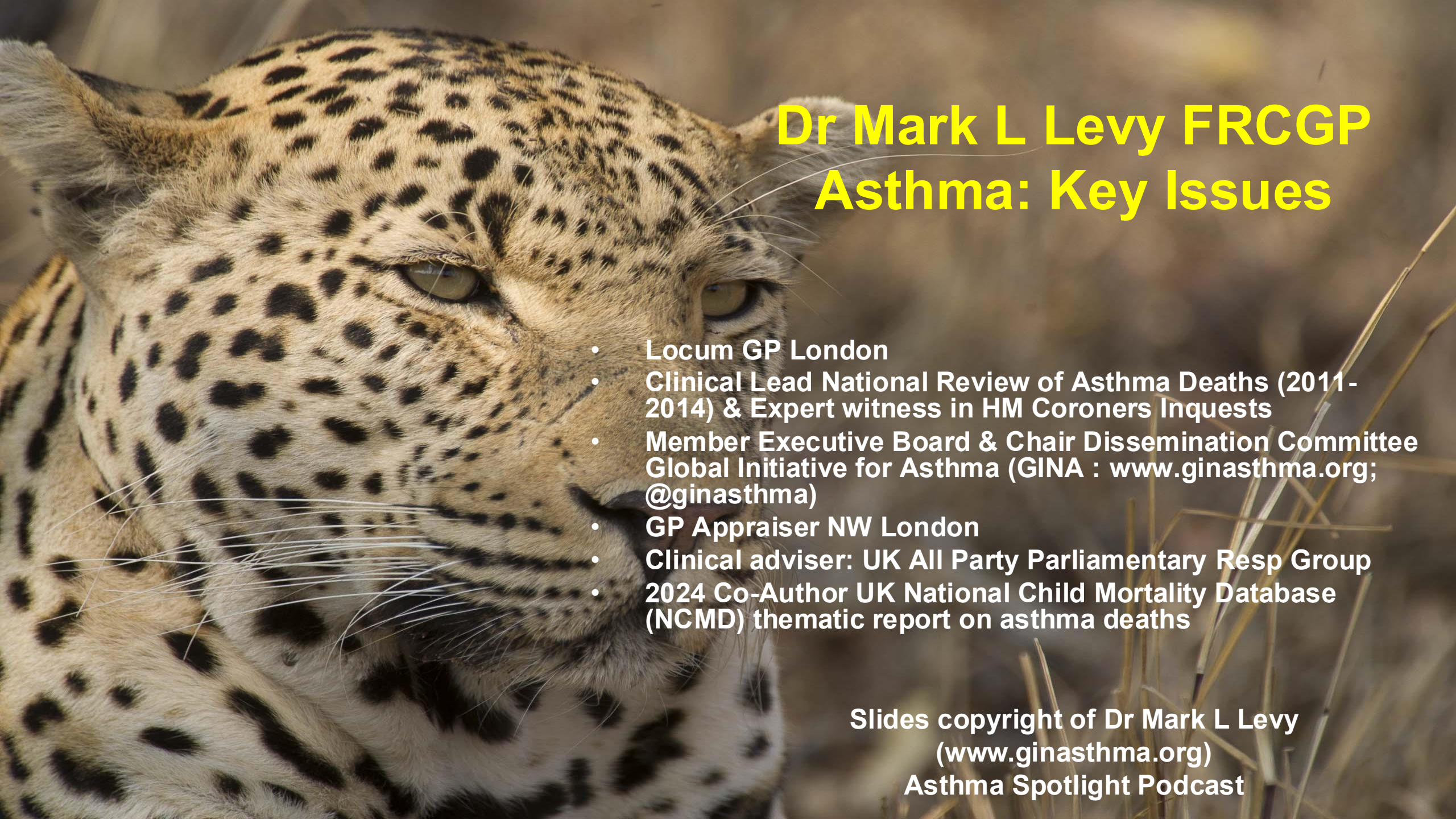

Dr Mark L Levy FRCGP
Asthma: Key Issues

- Locum GP London
- Clinical Lead National Review of Asthma Deaths (2011-2014) & Expert witness in HM Coroners Inquests
- Member Executive Board & Chair Dissemination Committee Global Initiative for Asthma (GINA : www.ginasthma.org; @ginasthma)
- GP Appraiser NW London
- Clinical adviser: UK All Party Parliamentary Resp Group
- 2024 Co-Author UK National Child Mortality Database (NCMD) thematic report on asthma deaths

Asthma Spotlight Podcast

Asthma Podcast- Dr Mark L Levy On Apple, Spotify and www.bigcatdoc.com

- Asthma Spotlight Podcast:
- https://bit.ly/3P1mJLC ;
- https://bit.ly/433fvwj and
- https://bit.ly/3V32qkt

- Please share with colleagues and people with asthma and parents of children with asthma

Asthma: Key Issues

- Two Case Histories – Recent Regulation 28 Cases
- Asthma : Key Issues – 5 Actions
  - Record diagnosis and inform patient/parent/carer
  - End Dangerous prescribing
  - Asthma Attack : A Red Flag for a Chronic Disease
    - Identify major risks of asthma death
    - Only discharge home when safe
    - Recognise that Asthma is a Chronic Disease

Preventable Asthma Death Billie Wicks : Date of Death: 15.9.2024 (Age 16 years) HM Coroners Inquest 6.3.2025

- Saw GP - Coughing , wheezing Short of Breath; O/E wheeze / hypoxia (94%)
  - Nebulised Salbutamol -> wheeze and hypoxia improved (98%)
  - Prescribed SABA (salbutamol) inhaler and antibiotic
- 6 days later: Still wheezing, coughing. Rash improved with antihistamine
- 2 days later: A&E 23:30 – Brief examination, 'mild wheeze'; C-XRay, OBS: Raised Resp and Pulse rates, Reduced SaO2 – measured twice and abnormalities persisted
- Next AM: Discharged 03:30 – She died midday
- Post-Mortem: Unequivocal - Acute and Chronic Asthma

Asthma or suspected Asthma never recorded

Peak Expiratory Flow Never measured

Asthma Diagnosed after death

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Asthma Spotlight Podcast

Preventable asthma death William Gray
Date of Death: 29.5.2021
HM Coroners Inquest : 22 November 2023:

News › Essex News › NHS

William Gray inquest: Death of Essex boy with asthma 'contributed to by neglect' coroner finds

William Gray, ten, died after a serious asthma attack in May 2021. A coroner has now concluded there were multiple failings in his care and his voice was "nowhere to be heard" before his "avoidable" death

NEWS By Ellis Whitehouse Chief Reporter
13:16, 22 NOV 2023

Enter your postcode for local news and info — Enter your postcode — Go — In YourArea

William Gray, ten, from Southend-on-Sea, had a "heart of gold", his mother said (Image: Family handout)

- Life-threatening attack Oct 2020 – requiring resuscitation by mom
- Paramedics
- Discharged A&E within 4 hours (without referral to a specialist)
- No ICS prescribed until one week later after nurse call from community
- GP then prescribed four short courses of oral corticosteroids for repeated asthma attacks in December 2020, February, April and May 2021.
- 25 May 2021 – Senior GP Nurse innapropriately delegated to do post attack review – .....failed to recognise risk / escalate care

The knowledge that William had had a life-threatening attack plus these four additional attacks treated by the practice should have led to a referral to an asthma specialist by the GP. (NRAD 2014 and numerous Coroner's regulation 28 Reports to prevent future deaths)

Levy, Fleming, Bush: UK Child asthma deaths – the last straw! Online BJGP April 2024

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Asthma Spotlight Podcast

Five Steps to end asthma attacks and deaths

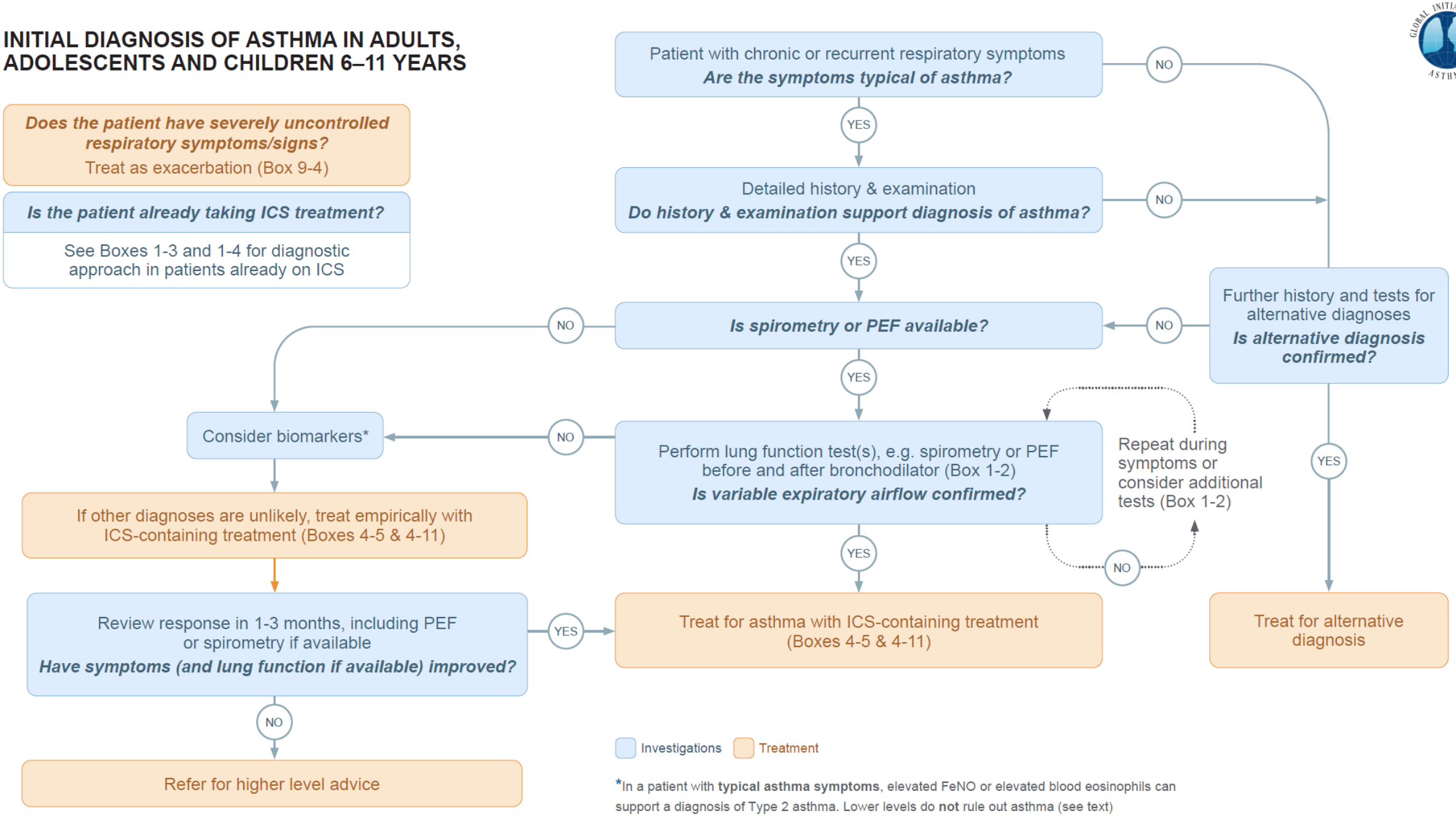
- Record diagnosis and inform patient/parent/carer
- End Dangerous prescribing
- Asthma Attack : A Red Flag for a Chronic Disease
  - Identify major risks of asthma death
  - Only discharge home when safe
  - Recognise that Asthma is a Chronic Disease

Wheeze is a symptom of airflow obstruction

- Wheeze is a symptom not a diagnosis
- Wheezing (even if its ‘mild’) is heard when there is > 20% airflow obstruction Noviski et al. Arch Dis Child. 1991;66(8):952-5.
- Asthma is the commonest Chronic Non-Communicable Disease in Childhood
- It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough, that vary over time and in intensity, together with variable expiratory airflow. Airflow limitation may later become persistent.

www.ginasthma.org

INITIAL DIAGNOSIS OF ASTHMA IN ADULTS, ADOLESCENTS AND CHILDREN 6–11 YEARS



*In a patient with **typical asthma symptoms**, elevated FeNO or elevated blood eosinophils can support a diagnosis of Type 2 asthma. Lower levels do **not** rule out asthma (see text)

Diagnosis of asthma in children aged 5 years and younger

1

Recurrent acute wheezing episodes

OR

At least 1 acute wheezing episode with asthma-like symptoms between episodes

+

2

No likely alternative cause for the respiratory symptoms

+

3

Timely clinical response of respiratory symptoms or signs to asthma medications

Any of:

- **Short-term response to SABA** within minutes during acute wheezing episode in healthcare setting (or, for more severe episode, within 3-4 hours after SABA and OCS started)
- **Short-term response to SABA at home** (within minutes)
- **Reduced frequency or severity** of acute wheezing episodes and/or of symptoms between episodes during 2–3 months' trial of daily ICS

All three criteria are needed for the diagnosis of asthma in children 5 years and younger

Acute wheezing episode: symptoms such as wheezing on expiration, accessory muscle use, or difficult, fast or heavy breathing, lasting for more than 24 hours

Asthma-like symptoms between episodes (also called *interval symptoms*): symptoms such as dry cough or wheeze after running, laughing or crying, or during sleep, that occur between acute wheezing episodes

If only 1 or 2 criteria are met, describe as 'suspected asthma', and continue follow-up

A personal or family history of allergic disease may strengthen the diagnosis of asthma, but is not required, and is not specific for asthma

If ‘Asthma’ or ‘Suspected Asthma’ was written in Billie’s record she may be alive today!

- Record Wheeze in record if confirmed by clinician
- Record ‘Asthma’ or ‘Suspected Asthma’ in any CYP prescribed salbutamol / bricanyl (SABAs) in an inhaler or via a nebulizer

  ..... Unless there is another specific diagnosis – eg Bronchopulmonary dysplasia / CF ....
- Any doubt ...refer to respiratory specialist

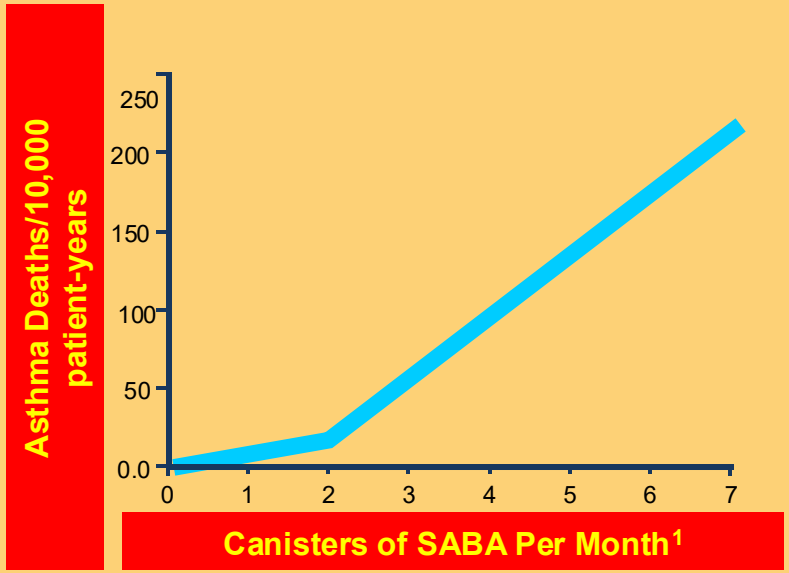
For asthma in preschool children see GINA 2025 Chapter 10

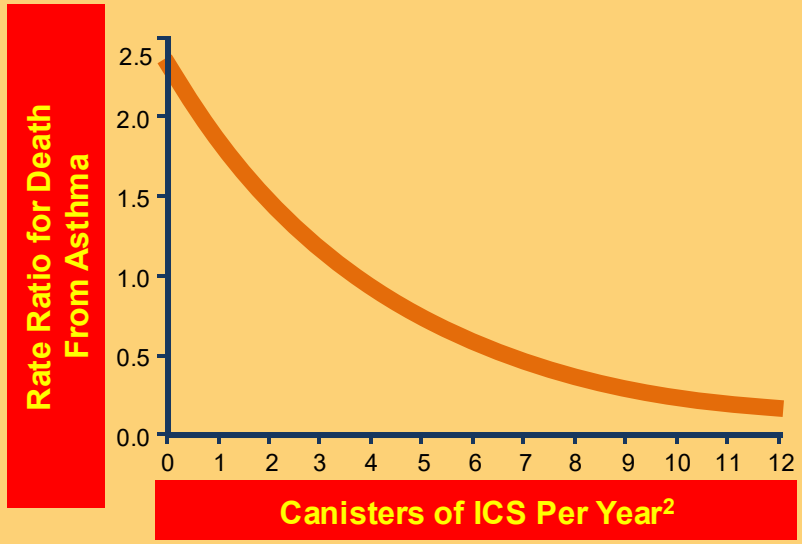
www.bigcatdoc.com
Asthma Spotlight Podcast

Five Steps to end asthma attacks and deaths

- Record diagnosis and inform patient/parent/carer
- End Dangerous prescribing
- Asthma Attack : A Red Flag for a Chronic Disease
  - Identify major risks of Attacks and Death
  - Only discharge home when safe
  - Recognise that Asthma is a Chronic Disease

Risks of overuse of SABAs (salbutamol/terbutyline) and underuse of Inhaled Corticosteroids have been known for over 30 Years





ICS, inhaled corticosteroid; SABA, short-acting β2-agonist.

1. Suissa S, *et al. Am J Respir Crit Care Med* 1994;149:604–10;
2. Suissa S, *et al. N Engl J Med* 2000;343:332–6;

EDITORIAL
GINA 2019

GINA 2019: a fundamental change in asthma management

Treatment of asthma with short-acting bronchodilators alone is no longer recommended for adults and adolescents

Helen K. Reddel[1], J. Mark FitzGerald[2], Eric D. Bateman[3], Leonard B. Bacharier[4], Allan Becker[5], Guy Brusselle[6], Roland Buhl[7], Alvaro A. Cruz[8], Louise Fleming[9], Hiromasa Inoue[10], Fanny Wai-san Ko[11], Jerry A. Krishnan[12], Mark L. Levy[13], Jiangtao Lin[14], Søren E. Pedersen[15], Aziz Sheikh[16], Arzu Yorgancioglu[17] and Louis-Philippe Boulet[18]

Background to changes in 2019 - the risks of SABA-only treatment

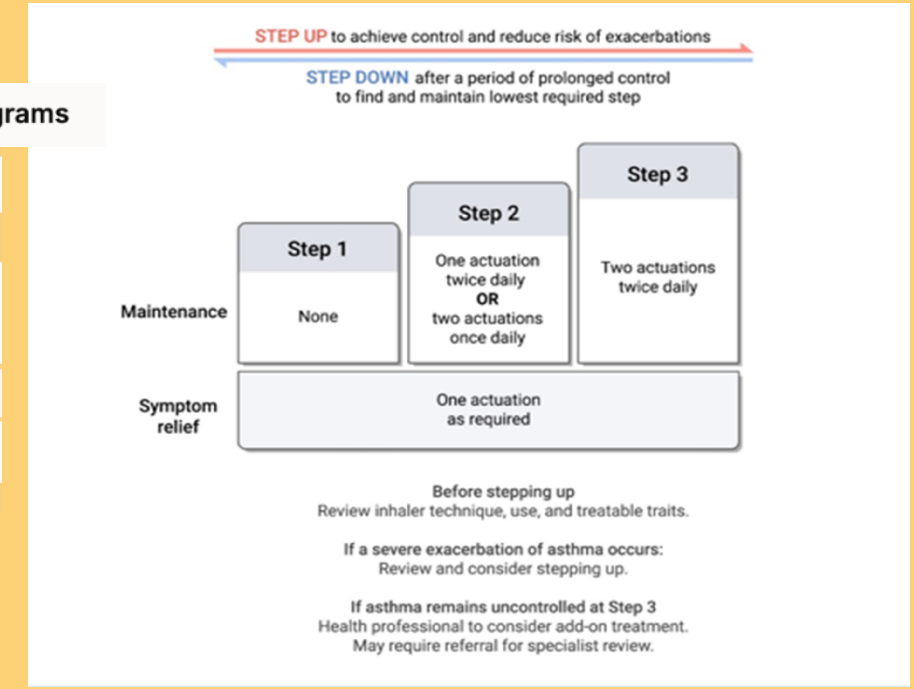
- Regular or frequent use of SABA is associated with adverse effects
  - β-receptor downregulation, decreased bronchoprotection, rebound hyperresponsiveness, decreased bronchodilator response *(1.Hancox, Respir Med 2000)*
  - Increased allergic response, and increased eosinophilic airway inflammation *(2.Aldridge, AJRCCM 2000)*
- Higher use of SABA is associated with adverse clinical outcomes
  - Dispensing of ≥3 canisters per year (average 1.7 puffs/day) is associated with higher risk of emergency department presentations *(3.Stanford, AAAI 2012)*
  - Dispensing of ≥12 canisters per year is associated with higher risk of death *(4.Suissa, AJRCCM 1994)*

Ref:
1.Hancox, Respir Med 2000
2.Aldridge, AJRCCM 2000
3. Stanford, AAAI 2012
4. Suissa, AJRCCM 1994

Anti-inflammatory reliever therapy (AIR)

- **Inhaled Corticosteroids + formoterol (fast acting, long acting beta-agonist bronchodilator) in one inhaler**

- DuoResp Spiromax® 160micrograms/ 4.5micrograms
- Fobumix® 160/4.5 Easyhaler
- Fobumix® 80/4.5 Easyhaler
- Symbicort 100/6 Turbohaler®
- Symbicort 200/6 Turbohaler®
- Symbicort® 100/3 pressurised inhaler
- WockAIR® 160micrograms/4.5micrograms



Levy ML, Beasley R, Bostock B, et al. British Journal of General Practice. 2024;74(739):86-9.

Image kindly shared by Professor Richard Beasley

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Asthma Spotlight Podcast

Evidence for AIR-only with ICS-formoterol

- ~10,000 patients with mild asthma
- Compared with SABA alone
  - Severe exacerbations reduced by 65%
  - ED visits/hospitalisations reduced by 65%
  - Small improvements in FEV_1, symptom control, QoL
- Compared with daily ICS + as-needed SABA
  - Similar or lower risk of severe exacerbations
  - Risk of ED visits/hospitalisations reduced by 37%
  - No clinically important differences in symptoms, lung function, QoL
  - Very low ICS dose
  - No need for daily treatment
  - Preferred by most patients (qualitative research)
- Not just an anti-inflammatory effect
  - Benefits patients with T2-low or T2-high biomarkers
- Approved by regulators in ~50 countries

Evidence for MART with ICS-formoterol

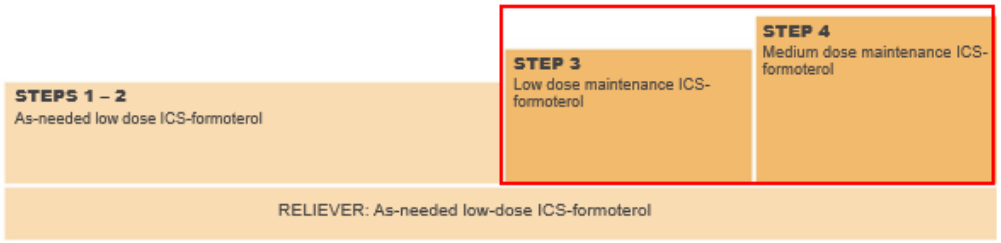
- ~30,000 patients with moderate-severe asthma
- Compared with regimens with a SABA reliever, MART reduces risk of severe exacerbations…
  - By 32% compared with same dose ICS-LABA
  - By 23% compared with higher dose ICS-LABA
  - By 17% compared with conventional best practice (in patients not required to have exacerbation history)
- Similar or better symptom control
- Lower maintenance ICS dose
- Not just an anti-inflammatory effect
  - Formoterol reduces exacerbations vs SABA, but greatest benefit is with ICS-formoterol reliever
  - Benefits patients with low or high blood eosinophils
- Approved by regulators in ~120 countries

For references, see GINA 2025 report

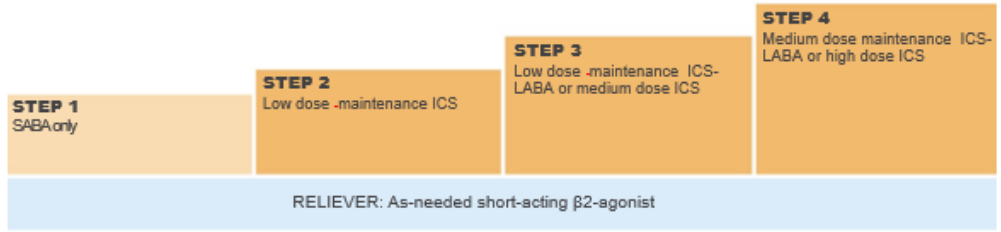
CARE-UK
ASTHMA STUDY

https://careukstudy.uk/

AIR As needed or part of MART:
ICS/formoterol
(intervention)

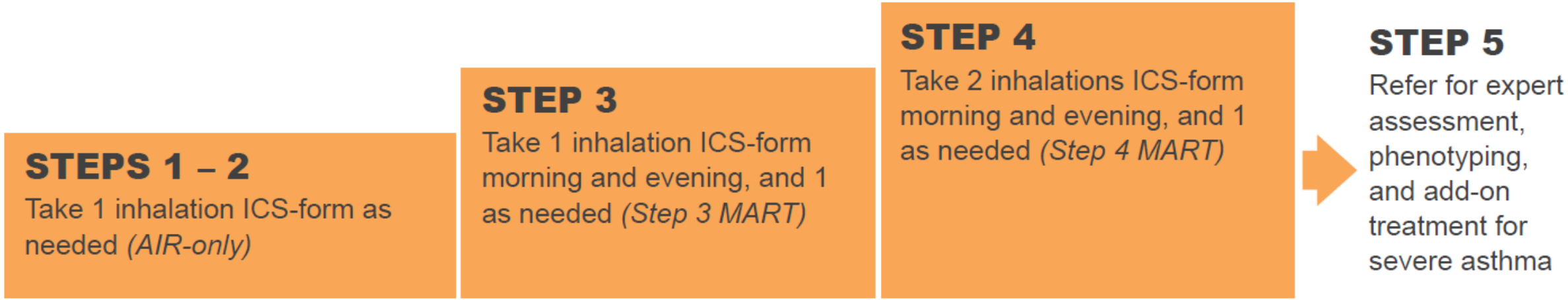


Current standard of care:
SABA +/ - ICS
(control)



- 1352 children (aged 6 – 11 years) enrolled across 20 – 25 sites in UK
- Clinician diagnosed asthma
- Prescribed SABA as a reliever

Example of GINA Track 1 with ICS-formoterol reliever



These examples are for budesonide-formoterol 160/4.5 mcg or BDP-formoterol 100/6 mcg, DPI or pMDI. See Box 4-8 for other formulations.

TRACK 1, Steps 1–4: the **PREFERRED** treatment for adults and adolescents.

Using ICS-formoterol as an anti-inflammatory reliever (AIR), with or without maintenance ICS-formoterol, reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen, with a single medication and dose across treatment steps.

Check local payer eligibility criteria for medications and doses

Terminology: AIR, AIR-only and MART

Maintenance-and-reliever therapy (MART) with ICS-formoterol

As-needed-only ICS-formoterol ('AIR-only')

TRACK 1: PREFERRED CONTROLLER and RELIEVER
Using ICS-formoterol as the reliever* reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen

STEPS 1 – 2
AIR-only*: low-dose ICS-formoterol as needed

STEP 3
MART* with low-dose maintenance ICS-formoterol

STEP 4
MART* with medium-dose maintenance ICS-formoterol

STEP 5
Add-on LAMA
Refer for assessment of phenotype. Consider trial of high-dose maintenance ICS-formoterol. Consider anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed low-dose ICS-formoterol*

*An anti-inflammatory reliever (AIR)

Anti-inflammatory reliever therapy (AIR)

- **Inhaled Corticosteroids + formoterol (fast acting, long acting beta-agonist bronchodilator) in one inhaler**

- DuoResp Spiromax® 160micrograms/ 4.5micrograms
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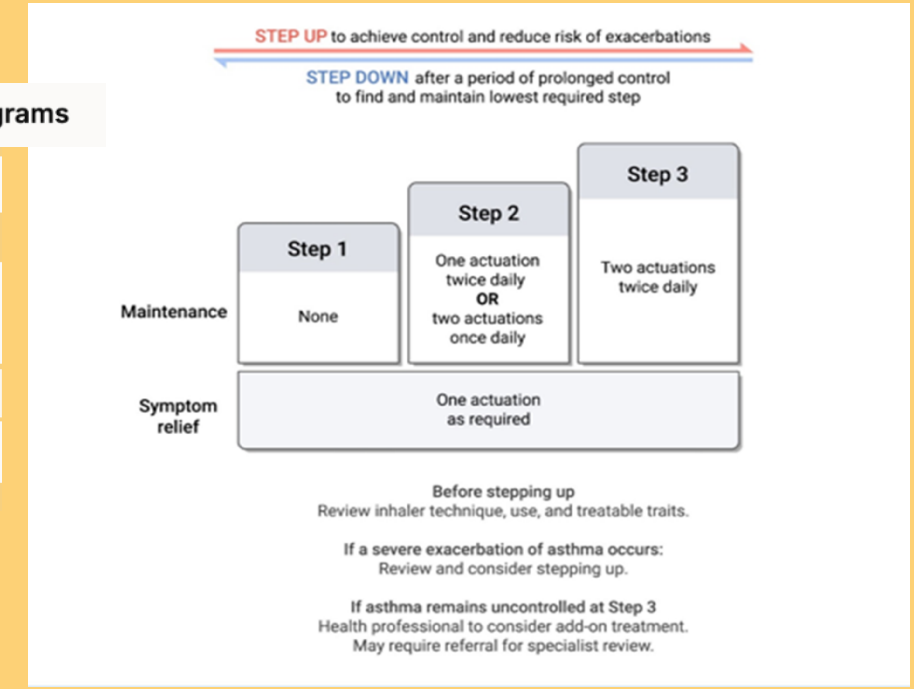

Levy ML, Beasley R, Bostock B, et al. British Journal of General Practice. 2024;74(739):86-9.

Image kindly shared by Professor Richard Beasley

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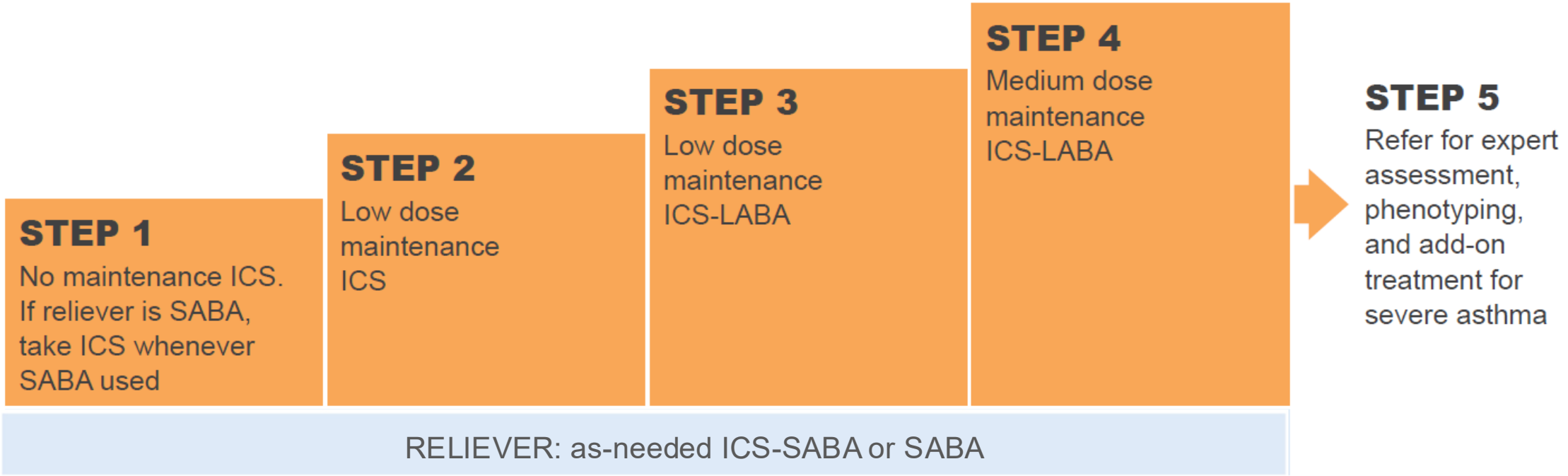
GINA Track 2 with SABA or ICS-SABA reliever



TRACK 2, Steps 1–4: Alternative CONTROLLER and RELIEVER for adults and adolescents.

Before considering a regimen with SABA reliever, check if the patient is likely to adhere to daily ICS treatment. If controller and reliever are in different types of inhaler device, or if changing steps requires a change in device, train patient in the correct inhaler technique.

Had Billie and William been prescribed Inhaled Corticosteroids they might still be alive

- Salbutamol or Terbutyline (SABAs) must never be prescribed for asthma /suspected asthma without an inhaled corticosteroid
- Inhaled Corticosteroids alone or in combination with a fast acting, long-acting bronchodilator – regularly or ‘as-needed for symptoms’ together with a bronchodilator

GINA – www.ginasthma.org / NICE/BTS/SIGN 2025

Levy et al. British Jnl of Gen Prac. 2024;74(739):86-9.

Five Steps to end asthma attacks and deaths

- Record diagnosis and inform patient/parent/carer
- End Dangerous prescribing
- **Asthma Attack : A Red Flag for a Chronic Disease**
  - Identify major risks of asthma death
  - Only discharge home when safe
  - Recognise that Asthma is a Chronic Disease

bitly

Acute Asthma

When treating attacks, important to assess severity to identify risk factors to prevent asthma death
Eg LTA/Severe asthma /
≥ 3 asthma drugs/obesity/Food allergy...

LTA=Life Threatening Attack

Clinical signs in acute asthma: Table 17: SIGN/BTS 158, 2019

Anyone with asthma or treated with inhalers who consults with Cough, Wheeze or Shortness of Breath

Ensure reception staff are trained to alert doctor immediately if a patient is short of breath

It is very important to identify those who have features of Acute Severe or Life-threatening asthma

SIGN/BTS 158, 2019/ NICE 2025

Table 17: Levels of severity of acute asthma attacks in children[639]

Moderate acute asthma	Able to talk in sentences SpO_2 ≥92% PEF ≥50% best or predicted Heart rate: ≤140/min in children aged 1–5 years; ≤125/min in children >5 years Respiratory rate: ≤40/min in children aged 1–5 years; ≤30/min in children >5 years	
Acute severe asthma	Can't complete sentences in one breath or too breathless to talk or feed SpO_2 <92% PEF 33–50% best or predicted Heart rate: >140/min in children aged 1–5 years; >125/min in children >5 years Respiratory rate: >40/min in children aged 1–5 years; >30/min in children >5 years	
Life-threatening asthma	Any one of the following in a child with severe asthma:	
	Clinical signs	**Measurements**
	Exhaustion	SpO_2 <92%
	Hypotension	PEF <33% best or predicted
	Cyanosis	
	Silent chest	
	Poor respiratory effort	
	Confusion	

www.bigcatdoc.com
Asthma Spotlight Podcast

Had BW and WG seen an asthma specialist they might be alive today

- RISK FACTORS (many modifiable)
- William
  - Had previous life-threatening event
  - Excess SABAs / Insufficent Inhaled Corticosteroids
  - 4 acute attacks in 7 months
  - One Post-Attack Review by untrained nurse
- Billie
  - Presented with first attack (apparently)
  - Had documented response to acute asthma treatment
  - Asthma/Suspected Asthma NOT diagnosed or recorded
  - Was prescribed SABA without ICS and without recording diagnosis
  - Rash responded to antihistamines
  - Wheeze confirmed by clinicians on auscultation
  - Asthma diagnosed at Post-Mortem

Five Steps to end asthma attacks and deaths

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  - Identify major risks of asthma death
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Clinical signs in acute asthma: Table 17: SIGN/BTS 158, 2019 and NICE/SIGN/BTS 2025

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	Cyanosis	
	Silent chest	
	Poor respiratory effort	
	Confusion	

Asthma control: Risk factors for asthma exacerbations

Uncontrolled asthma symptoms increase the risk of exacerbations

Factors associated with increased exacerbation risk, even in patients with few symptoms:

- SABA over-use, e.g., ≥3 canisters of salbutamol in 12 months (average daily use)
- Inadequate ICS (not prescribed, poor adherence, incorrect inhaler technique)
- Comorbidities (obesity, chronic rhinosinusitis, GERD, confirmed food allergy, pregnancy)
- Exposures (smoking, vaping, air pollution, allergen exposure if sensitized)
- Psychosocial or socioeconomic problems
- Low lung function
- High blood eosinophils or FeNO
- History of severe exacerbations

Supported by recent meta-analysis of data for many of these risk factors from the placebo arms of 22 clinical trials (ORACLE2 study, Meulmeester et al, Lancet Respir Med 2025)

People with infrequent symptoms can still have severe, life-threatening or fatal exacerbations

Five Steps to end asthma attacks and deaths

- Record diagnosis and inform patient/parent/carer
- End Dangerous prescribing
- Asthma Attack : A Red Flag for a Chronic Disease
  - Identify major risks of asthma death
  - Only discharge home when safe
  - Recognise that Asthma is a Chronic Disease

Asthma is a Chronic Disease

Acute attacks are a signal that something serious has gone wrong with chronic treatment ...
A post-attack review is part of the treatment of an attack to identify modifiable risk factors and optimize care to prevent further attacks

Asthma control: Risk factors for asthma exacerbations

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Supported by recent meta-analysis of data for many of these risk factors from the placebo arms of 22 clinical trials (ORACLE2 study, Meulmeester et al, Lancet Respir Med 2025)

People with infrequent symptoms can still have severe, life-threatening or fatal exacerbations

Post asthma attack review (< 2 days) by someone appropriately trained

Is the attack over?

Yes

Why did the attack happen

- Poor symptom control
- Failure to recognise risk

No

ACTION

Admit to Hospital

Optimise treatment

Review again

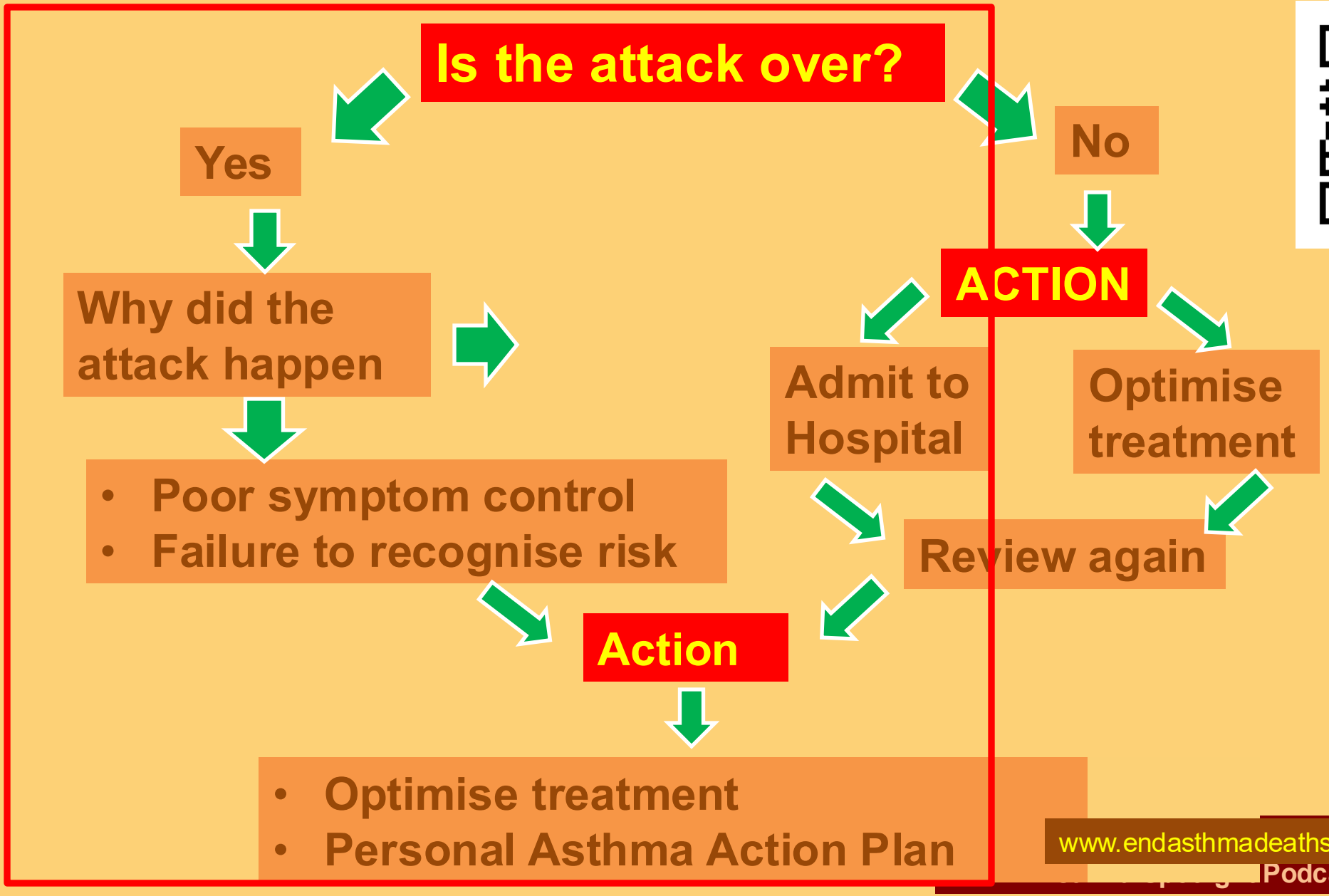
Action

- Optimise treatment
- Personal Asthma Action Plan

www.endasthmadeaths.wordpress.com

Podcast

Post asthma attack review (< 2 days) by someone appropriately trained



www.endasthmadeaths.wordpress.com

Podcast

GINA 2025 - personalized asthma management

REVIEW

- Symptoms
- Exacerbations
- Side-effects
- Comorbidities
- Lung function
- Consider biomarkers
- Patient (and parent/caregiver) satisfaction

ASSESS

- Confirmation of diagnosis if necessary
- Symptom control & modifiable risk factors
- Comorbidities
- Inhaler technique & adherence
- Patient (and parent/caregiver) preferences and goals

ADJUST

- Treatment of modifiable risk factors and comorbidities
- Non-pharmacological strategies
- Asthma medications including ICS
- Education & skills training, action plan

GINA Resources

www.ginasthma.org

- GINA Strategy Report 2025
- GINA Summary Guide 2025
- GINA Severe Asthma Guide 2025
- GINA Slide Sets 2025
- GINA Podcasts 2025

Summary: Actions to prevent asthma attacks/deaths

- Record diagnosis of asthma / suspected asthma and inform
- No one is prescribed SABA (salbutamol) alone without prescribing an inhaled corticosteroid (regularly or as needed in combination with a bronchodilator)
- Identify major risks for asthma death
- Only send home when safe – (ie not needing SABA ≥ 4 hourly ; safe /stable lung function – ie PEF in prim care)
- Recognise asthma attack is a red flag for identifying risk and optimizing care for the chronic asthma
  - Perform a post-attack review – someone trained